510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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APR 2 9 2004

VersaBond® AB Bone Cement

Submitter:	Smith & Nephew, Inc.
Submitter's address:	1450 Brooks Road Memphis, TN 38116
Submitter's phone number:	901-399-6487
Contact person:	David Henley
Date summary prepared:	April 27, 2004
Trade or proprietary name:	*VersaBond® AB Bone Cement*
Common or usual name:	Polymethylmethacrylate (PMMA) Bone Cement (antibiotic loaded)
Classification name and reference:	21 CFR 888.3027, polymethylmethacrylate (PMMA) bone cement – Class II
Device product code and panel code:	Orthopedics / 87 / LOD

Device Description

VersaBond® AB Bone Cement consists of two separate components: polymer powder and monomer liquid. The two components are packaged together and are pre-measured, sterilized components which, when mixed, form a radiopaque, rapidly setting bone cement.

Device Intended Use

VersaBond® AB Bone Cement with Gentamicin is indicated for the fixation of prostheses to living bone for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Technological Characteristics

VersaBond® AB Bone Cement is similar to VersaBond® Bone Cement (i.e. non-antibiotic). Similarities include the identical chemical constituents for the bone cement, except that an antibiotic has been added to *VersaBond® AB Bone Cement*. Plain VersaBond® Bone Cement also shares similar indications for use and technological characteristics. With regard to the antibiotic, Palacos® G Bone Cement with Gentamicin (K030086), marketed by Biomet, Inc., is a predicate device that uses the identical, but common antibiotic.

Substantially Equivalent Device

- VersaBond® Bone Cement, K001160 and K033509 (without antibiotic) - Smith & Nephew, Inc.
- AMC Antimicrobial Pin/Wire Sleeve, K012193 (for use of gentamicin antibiotic) - Smith & Nephew, Inc.
- Surgical Simplex P®, PMA N17004 (without antibiotic) – Howmedica Osteonics, Inc.
- Palacos® G Bone Cement w/Gentamicin, K030086 – Biomet, Inc.
- Palacos® R Bone Cement, PMA P810020 – EM Industries, Inc.

Performance Characteristics

Device evaluation and testing has indicated that *VersaBond® AB Bone Cement* is substantially equivalent to plain VersaBond® Bone Cement, Palacos R, and Simplex.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Orthopedics
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K022688
Trade/Device Name: VersaBond™ AB Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD and MBB
Dated: January 30, 2004
Received: February 5, 2004

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

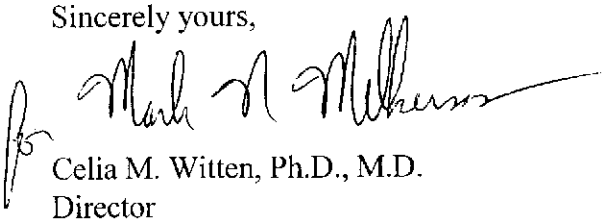
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 022688

INDICATIONS for USE STATEMENT

K022688

VersaBond® AB Bone Cement

Indications for Use:

VersaBond® AB Bone Cement with Gentamicin is indicated for the fixation of prostheses to living bone for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Prescription Use Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millers

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K022688